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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,883	12/21/2001	Toshio Miyata	SHIM012	2901

24353 7590 02/08/2005

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,883

Applicant(s)

MIYATA, TOSHIO

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-7, 11,-13, 15-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,11-13,15-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/20/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed December 27, 2004 is acknowledged and has been entered.

Rejections Withdrawn

The rejection of claims 1, 3, and 5 under 35 U.S.C. 112 first paragraph is withdrawn in view of the amendments to the claims.

The rejection of claims 1, 3, 5, and 6-18 as being vague and indefinite is withdrawn in view of the amendments to the claims.

The rejection of claims 6 and 7 as being anticipated by Tsumimoto et al is withdrawn in view of the amendments to the claims.

The rejection of claims 6-9 and 11-18 as being unpatentable over Gombinski in view of Tsujimoto et al is withdrawn in view of the amendments to the claims.

The rejection of claims 6-11 as being unpatentable over Rohr in view of Tsujimoto et al is withdrawn in view of the amendments to the claims.

Claim Objections

1. Claim 12 is objected to because of the following informalities: Claim 12, line 3 the recitation "for a first antibody megsin protein complex" should be --form a first antibody megsin protein complex--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 5 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyata et al. (WO 99/15652) in light of Kurokawa (EP 1018551).

Miyata et al disclose polyclonal and monoclonal antibodies recognizing Megsin protein (p. 7 Kurokawa). Miyata et al disclose that these antibodies can be used in diagnosing diseases related to mesangial cells (p 7 Kurokawa). Miyata et al disclose that biological samples such as blood or urine is measured for Megsin protein (page 8). Miyata et al disclose determining the levels of Megsin in IgA nephropathy patients and normal patients. Miyata et al discloses that the levels of Megsin protein is elevated in IgA nephropathy patients as compared to normal patients (p. 2 Kurokawa).

It is noted that Kurokawa (EP 1018551) is international publication number (WO 99/15652) (see cover page of EP 1018551). Therefore EP 1018551 is the English equivalent of WO 99/15652.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6, 7, 12, 13 and 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Miyata et al (WO 99/15652) in light of Kurokawa (EP 1018551)

Gombinski disclose methods for detecting and determining biological entities in a test sample. Gombinski disclose magnetic particles which may have antibodies immobilized on the surface of the particles. Gombinski disclose that these magnetic particles containing the immobilized antibody will bind to the biological entity. Gombinski disclose that this biological entity can be a protein (col 3 and 4). Gombinski disclose that the magnetic particle containing the immobilized antibody and the biological entity can be further subjected to antibodies linked to detectable markers (marker molecule) to detect the biological entity (col 12, lines 49-67). Gombinski disclose the use of a magnet with the magnetic particles. Gombinski disclose kits for carrying out the methods (col 10 and abstract). Gombinski disclose that the sample can be any type of liquid media which may contain the biological entity to be detected.

Gombinski differ from the instant invention in failing to teach the antibodies are anti-megsin antibodies that recognizes a polypeptide consisting of the amino acid sequence of SEQ ID NO: 12 and SEQ ID NO: 11.

Miyata et al disclose antibodies that recognize the amino acid sequence FREMDDNQGNVFF same as SEQ ID 11 of applicants specification on page 28 and antibodies that recognize SQSGLQSQLKRVFSD, same as SEQ ID 12 of applicants

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specification on page 28 (see Kurokawa p. 15). Miyata et al disclose that the antibodies can be immobilized on insoluble carriers and can be labeled (see page 7 of Kurokawa).

Miyata et al disclose that the antibodies can be polyclonal or monoclonal.

It would have been obvious to one of ordinary skill in the art to use the antibodies taught by Miyata et al in the method and kit of Gombinski because Gombinski is generic with respect to the biological entity (analyte) that is to be detected and one would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case megsin protein.

The 102 and 103 rejections above were necessitated because of the intervening reference of Miyata et al (WO 99/15652).

The 102 and 103 rejections above may be overcome with a perfection of the priority document which includes a certified English translation of the priority document and support for the claimed subject matter.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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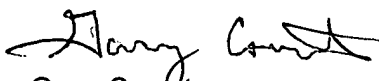
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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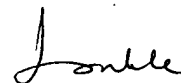


Gary Counts

Examiner

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January 28, 2005



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02/04/05